

Stem Cell Agency's Governing Board Proposes Dramatic Changes in Response to IOM Report

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San Francisco, CA – The Governing Board of California's stem cell agency, the California Institute for Regenerative Medicine (CIRM), has adopted a framework of proposals that could dramatically change some aspects of its work, in order to address recommendations from the Institute of Medicine (IOM).

The IOM report, issued in December, made recommendations on a range of issues from the structure of the agency's Board to the role of patient advocates on advisory committees.

In response to those recommendations the Independent Citizens Oversight Committee (ICOC), the Governing Board of the agency voted to endorse a framework of changes that will be open for public input until the March Board meeting when a final vote will be taken on the changed policies, regulations and by-laws implementing the plan adopted on January 23. The framework includes:

- The 13 Board members appointed from institutions eligible for funding from the stem cell agency, such as those in the University of California system, would no longer vote on any grants brought before the Board but would instead abstain
- All members of the Board would be able to participate in discussions on applications but only patient advocates and independent members of the Board would be able to vote on funding issues (members would continue to refrain from any discussion of specific applications from their institutions)
- Patient Advocates would continue to be members of the Grants Working Groups but would not vote on individual applications
- Programmatic review, aimed at balancing the agency's portfolio, would take place at public Board meetings where members have a chance to make changes to recommendations from the Grants Working Group
- Industry involvement would increase, where appropriate, on the Grants Working Group, and also feature in a newly constituted Scientific Advisory Board; the structure and membership of this group is still under discussion
- Appeals on applications not recommended for funding will be handled by science staff who will evaluate them, determine if they merit further review by the Grants Working Group, and ultimately make recommendations to the Board. Staff will also be allowed to advocate for additional grants not recommended for funding by the Grants Working Group that they believe should be considered in programmatic review
- The Chair and President would share a division of responsibilities with the President supervising all scientific operations and internal operational responsibilities. In addition the Chief Financial Officer would report to the President. The Chair would handle the 'external affairs' aspect of the agency, things such as financial sustainability to raise additional funds, state legislative relations, bond financing, public communications etc.
- IOM recommendation on the creation of a Scientific Advisory Board to provide counsel on such issues as funding priorities and portfolio strategy will be implemented by staff
- IOM recommendations on Intellectual Property will be referred to the agency's IP subcommittee which will review and report back to the full board with options and recommendations
- IOM recommendations on Sustainability: Chair, working with the President, will develop a plan to address this and present to the Board when ready

"These are big potential changes, and important ones," says Jonathan Thomas, JD, PhD, Chair of the Board. "We are proposing them to address the concerns of the IOM, and to demonstrate how seriously we take the recommendations detailed in their report."

The Board voted to approve the proposed framework, to continue to discuss the proposals before voting on the mechanics to implement them at the Board meeting in March. The vote also calls for the Board to review the changes after one year to determine if they are working and if any adjustments need to be made.

"One of the big issues raised by the IOM report was that our current governing structure created a perception of conflicts of interest in how we fund research," says Chairman Thomas. "While no one has found any actual conflicts, these changes directly address the broad public perception. By having Board members who belong to institutions that can get CIRM money abstain from all votes on funding we take even the perception of conflict of interest out of the picture. In addition having programmatic review at the Board will increase the transparency of the grant making process."

Harold Shapiro, PhD, head of the IOM panel that produced the report, commended the stem cell agency for its response to the recommendations saying: "The proposals you shared with me represent a very thoughtful and significant response to our recommendations and will, I believe, serve the long term interests of the citizens of California and the field of regenerative medicine. In particular these proposals take a significant step towards dealing with financial conflicts of interest, enhancing the credibility and integrity of the scientific review process, increasing the role of industry representatives, further clarifying the roles of the President and Board Chair, and establish the Scientific Advisory Board as the IOM Committee recommended."

The Board voted unanimously with one abstention in favor of the proposed framework after a vigorous and thoughtful debate during which even Board members who would no longer vote on funding issues expressed their support for the recommendations.

Michael Friedman, MD, CEO of City of Hope, said having to abstain on some votes is a small price to pay to demonstrate the integrity of the process: "This is necessary for ensuring the public trust and I think these compromises are essential to enable us to reassure the public about the integrity of the work we do and to be able to continue with our mission."

Chairman Thomas says the vote reflects the desire to move the agency forward in a constructive and decisive manner; "We must get past long-standing criticism on structure and protocol that has far too long stolen focus in the media, and with other outside observers, from the incredible scientific work that we have enabled."

At the meeting the Board also voted to approve the reappointment of 22 members of the Grants Working Group, the independent panel of experts that review applications for CIRM funding.

In addition the Board passed a resolution honoring Board member James Economou, MD, PhD, Vice Chancellor for Research at UCLA, who is stepping down. The Board praised Dr. Economou for his dedication and service to the stem cell agency and the people of California.

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research

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